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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,060	07/25/2001	Sigrid Cornelis	4976US	6077

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

19

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/915,060

Applicant(s)

CORNELIS ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4,11-15,23-25 and 27-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,11-15,23-25,27-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

This Office Action is a response to the "Amendment" filed 27 May 2003 (Paper No. 18), which is a reply to the Non-Final Office Action mailed 24 February 2003 (Paper No. 17). Claims 1, 4-7, 11-15, 23-25 and 27-36 were considered in Paper No. 17. Claims 1 and 5-7 were canceled, claims 4, 11, 12, 14, 25, 27 and 28 were amended and claims 37-40 were added in Paper No. 18. Claims 4, 11-15, 23-25 and 27-40 are pending and under consideration.

### ***Response to Amendment***

Rejection of claims 1 and 5-7 is rendered moot by cancellation of the claims.

#### **Claim Rejections - 35 USC § 112**

Rejection of claims 11-15, 23 and 24 under 35 U.S.C. 112, first paragraph, as lacking adequate written description is withdrawn.

Rejection of claims 25 and 27-35 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn.

#### **Claim Rejections - 35 USC § 102**

Claims 4, 11 and 12 stand rejected and newly added claims 37-40 are rejected under 35 U.S.C. §102(b) as anticipated by Xiang *et al.* for reasons of record. Clarification of the Examiner's position is set forth herein below in the response to arguments.

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Claims 25, 27-36 and 37-39 stand rejected under 35 U.S.C. §102(a) as anticipated by Gururajan *et al.* for reasons of record. Clarification of the Examiner's position is set forth herein below in the response to arguments.

Claims 13-15, 23 and 24 stand rejected under 35 U.S.C. §103(a) as obvious over Xiang *et al.* for reasons of record. Clarification of the Examiner's position is set forth herein below in the response to arguments.

### ***Response to Arguments***

In response to the outstanding art rejections, Applicant has amended the claims such that they are now directed to a "heterologous nucleic acid molecule" comprising various disclosed sequences, or to a nucleotide sequence comprising various disclosed sequences comprised within a heterologous sequence. Applicant asserts that the claims are now distinguished from the cited art based on the Examiner's statement, "because Xiang *et al.* does not teach any function associated with the sequence corresponding to the fragments identified in the instant application as a G2/M cell cycle-dependent IRES, it would not be obvious to excise those fragments from the nucleic acid taught by Xiang *et al.* or insert those fragments into a heterologous nucleic acid", found on page 3 of the previous office action. To clarify the Examiner's position, the non-obvious limitation is the nucleic acid fragment excised from the nucleic acid taught by the prior art, not a nucleic acid comprising that sequence wherein the nucleic acid is found in a heterologous nucleic acid. In other words, the distinguishing feature is the nucleic acid consisting of the nucleic acid sequences set forth as SEQ ID NO: 1 and 4-7.

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The amended claims are indefinite for reasons set forth herein below; however, given the broadest reasonable interpretation, claim 4, and claims depending therefrom, encompass any nucleic acid molecule comprising SEQ ID NO: 1 or 7; claim 25, and claims depending therefrom, encompass any nucleic acid molecule comprising SEQ ID NO: 4-6; and claim 37, and claims depending therefrom, encompass any nucleic acid molecule comprising SEQ ID NO: 1 and 4-7. This is because, as described below, the scope of the claim is not limited by the recitation of a heterologous nucleic acid molecule without a clear statement of what the nucleic acid molecule is heterologous to. In addition, claims directed to chimeric nucleic acid molecules which comprise a nucleic acid molecule comprising the disclosed sequences are not distinguished from the art because the art teaches vector constructs comprising the nucleic acids. As indicated in the previous office action, because the art does not teach any function associated with the sequence corresponding to the fragments identified in the instant application as a G2/M cell cycle-dependent IRES, it would not be obvious to excise those fragments from the nucleic acids taught in the art. However, any claim to a nucleic acid which is only limited to comprising the sequences set forth as SEQ ID NO: 1 or 4-7 still encompasses the nucleic acids disclosed in the prior art. Therefore the claims stand rejected for the reasons set forth in the previous office actions.

***New Grounds Necessitated by Amendment***

**Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 4, 11-15, 23-25 and 27-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 25, and claims depending therefrom, are indefinite in being directed to a “heterologous nucleic acid molecule”. The term “heterologous” is relative and its meaning is dependent upon to what the nucleic acid is compared. As all nucleic acids are heterologous to something (i.e., all nucleic acids obtained from one species are heterologous to nucleic acids or cells obtained from another species), the heterologous nucleic acid molecule of the claims is understood to encompass all nucleic acid molecules.

Claim 37, and claims depending from claim 37, are directed to a nucleic acid sequence comprised within a heterologous nucleic acid. As above, the metes and bounds of the claims are unclear because it is not clear to what the nucleic acid is heterologous.

It would appear that Applicant intends that the claimed nucleic acid molecules are chimeric (i.e., consisting of nucleic acids that are heterologous to one another) and amending the claims accordingly would obviate these grounds for rejection.

Claims 27-35 are additionally indefinite in being directed to genes, vectors and cells comprising the “nucleic acid sequence of claim 25”. Claim 25 is directed to a nucleic acid molecule comprising (as the phrase “consisting essentially of” is understood by the Office) a nucleic acid sequence selected from the group consisting of SEQ ID NO: 4, 5 and 6. It is unclear whether applicant intends that the products of the dependent claims comprise only those sequences set forth as SEQ ID NO: 4, 5 and 6 or the entire nucleic acid molecule of claim 10 which comprises sequence beyond the sequence set forth as SEQ ID NO: 4, 5 and 6. If the

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former were the case, substituting “molecule” for sequence would obviate this rejection. If the latter were the case, explicitly identifying the nucleic acid sequences comprised by the products (i.e., SEQ ID NO: 4, 5 and 6) would obviate this rejection.

Claim 37, and claims depending therefrom, are additionally indefinite in being directed to “a recombinant nucleotide sequence”. It is unclear whether applicant is claiming a composition of matter, which would be a nucleic acid molecule comprising the nucleotide sequence, or if applicant is claiming the sequence itself, which is an abstract representation of the nucleic acid molecule. Amending the claim such that it is directed to a recombinant nucleic acid molecule would obviate these grounds for rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448.

The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms  
July 31, 2003



**JAMES KETTER  
PRIMARY EXAMINER**